UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,578	08/20/2003	Patrick Jay Lutz	05408/100K559-US1	5199

7278 7590 04/27/2007

DARBY & DARBY P.C.
P. O. BOX 5257
NEW YORK, NY 10150-5257

EXAMINER	
LANDAU, SHARMILA GOLLAMUDI	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/644,578	LUTZ ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-11* is/are pending in the application.

4a) Of the above claim(s) *5 and 12-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I, claims 1-11 in the reply filed on 12/13/06 is acknowledged. Further, applicant election of dimethyloldimethylhydantoin and monomethyloldmethylhydantoin mixture as the aldehyde donors and dimethylhydantoin as the stabilizer is acknowledged. It s noted that applicant states that claim 5 is readable on the elected species, but this is incorrect. Thus, claim 5 is withdrawn as being directed to a non-elected species. The traversal is on the ground(s) that examination of all the claims does not present a serious burden. Applicant argues that a search for invention I would "uncover the prior art relevant to Groups II-IV". This is not found persuasive because: The criteria for restriction is not whether the examiner "happens" to find prior art on other inventions while searching the elected invention. The criteria for restriction is if the examiner can show a distinctness between each group and in instant case, the examiner has provided reasoning for the distinctness of each group. For instance, if the method of preparing a product can make a materially different product then the invention is shown to be distinct. In instant case, claim 12 makes a materially different product then claimed in Group I wherein the product comprises specific amounts of each component and a solvent. Moreover, it can be seen that the search of claim 1 does not necessarily encompass a search for invention II. Similarly, as stated in the Office Action the synergistic composition is distinct from the method of using the composition since the product may be used in a materially different process. This is enough to establish the distinctness between the inventions. For the distinctness between each group note the Office Action of 10/13/06 wherein the examiner has indicated the reasons for distinctness. Therefore, claims 1-4 and 6-11 directed

to the elected invention and species are pending and claims 5 and 12-19 are withdrawn as being directed to a non-elected invention and species.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is directed to a composition comprising three components: I) aldehyde donor; II) a stabilizer; and III) dehydroacetic acid or salt thereof. Claim 10 limit the second component to a weight percent of 0-30%. However, component II) is required by claim 1 and thus cannot be in a weight percent of 0. Thus, the metes and bounds of the claims are vague and indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 7, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hahn et al (5,804,203) as evidenced by US 4585656 and 20030207908.

Hahn et al disclose a composition comprising .05-.10% disodium EDTA (stabilizer); 0.2-0.30 imidazolidinyl urea (aldehyde donor); 0.1-0.30 methylparaben (stabilizer); and 0.05-0.2% sodium dehydroacetate, among other ingredients. See example 9.

US '656 discloses methyparaben as a stabilizer and US '908 discloses disodium EDTA as a stabilizer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn et al (5,804,203) in view of Dodd et al (2002/0176879).

The teachings of Hahn have been set forth above.

Hahn does not teach the instant dimethyloldimethylhydantoin ("DMDMH").

Dodd teaches imidazolidone compounds include instant DMDMH and imidazolidinyl urea. see 0179-184.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hahn et al and Dodd and substitute the prior art's imidazolidone compound (aldehyde donor) with the instant DMDMD imidazolidone compound. One would have been motivated to do so since Dodd teaches both instant DMDMH and the prior art's imidazolidinyl urea are both imidazolidone compounds used as preservatives. Therefore, it would have been obvious for a skilled artisan to substitute one imidazolidone compound for

another since the prior art establishes the functional equivalency of both, i.e. both are used as preservatives in cosmetic products.

Claims 1-4 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rothenburger et al (6,121,302) in view Willingham (5,424,324).

Rothenburger et al teach a highly stable formulation having broad-spectrum preservative properties. The formulation is an admixture of dialkanol-substituted dimethyhydantoin, one or more isothiazolone compounds, a hydantoin stabilizer, and a hydroxyl solvent. The formulation has a free formaldehyde content of less than 0.2% and is beneficial for preserving various aqueous compositions, including household and industrial products, and especially personal care products, which require a less acidic pH range than in which isothiazolone is stable in the presence of cationic salts. See abstract. Rothenburger teaches isothiazolone is highly toxic and very unstable under most circumstances, such as when present in water or other reactive molecule. To make the compound stable large amounts of cationic salts are added and the isothiazolone is diluted (usually to about 14% or less). While under these conditions, isothiazolone is stable at room temperature at low pH (from 1-4). During storage and manufacturing conditions the temperature and pH may increase causing isothiazolone to become unstable. While highly useful for controlling bacteria, fungi and other contaminating microbes in end-use products, isothiazolone's instability under less than ideal conditions results in a marked loss of activity. Thus, it would be advantageous to provide a preservative system that contains isothiazolone, which is stable at a broad range of temperature and pH.

The stable composition contains 20 to 95 wt % of a formaldehyde donor, 0.02 to 90 wt % of an isothiazolone, 1 to 30 wt % of a alkyl hydantoin stabilizer and up to 60 wt % of a hydroxyl

solvent. See claim 3. The formaldehyde donor is a 1,3-dimethylol-5,5-dimethylhydantoin, 1-methylol-5,5-dimethylhydantoin, 3-methylol-5,5-dimethylhydantoin or 1-methylol-3-methyloloxymethylene-5,5-dimethylhydantoin, or *mixtures thereof.* See claim 4. The stabilizer is 5,5-dimethyl hydantoin.

Rothenburger does not teach dehydroacetic acid in the composition.

Willingham teaches the use of carbonyl stabilizers for 3-isothiazoles. The formulation has a broad spectrum preservative. See column 3, lines 25-35. Willingham teaches some carbonyl compounds are known to have microbiocidal activity, although their efficacy as stabilizers of isothiazolones has not previously been appreciated. Such compounds are particularly desirable to use as stabilizers; examples are acrolein, benzoic acid, sorbic acid, dehydroacetic acid, glycolic acid and citric acid. The formulation comprises preferably 0.01-20% of the carbonyl compound. See column 4, lines 40-65.

It would have been obvious to one of ordinary skill in the art at the time the invention was made combine the teachings of Rothenburger and Willingham and further utilize dehydroacetic acid in the composition. One would have been motivated to do so since Willingham teaches dehydroacetic acid not only has a stabilizing effect on isothiazolones but also is known to have microbiocidal activity. Therefore, it would have been obvious for a skilled artisan to utilize dehydroacetic acid for its additive effect of further enhancing stability of isothiazole and increase the microbiocidal activity of the composition.

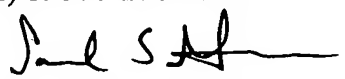
Conclusion

All the claims are rejected at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Sharmila S. Gollamudi
Primary Examiner
Art Unit 1616

SSG